NUVASIVE
Creative Spine Technology

OCT 1 6 2001

K013215

510(k) Summary

Submitter:	NuVasive, Inc. 10065 Old Grove Road, Suite A San Diego CA 92131
Contact person:	Sean M. Curry 16787 Bernardo Center Drive, Suite A San Diego, CA 92128
Phone:	(858) 675-8200
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Proprietary name:	NeuroVision JJB System
Common name:	Electromyography (EMG) monitor/stimulator
Classification:	868.2775
Product Code:	BXM
Classification name:	Nerve Stimulator, AC-Powered

Substantial equivalence claimed to:
K002677: NuVasive INS-1 Intraoperative Nerve Surveillance System

Description:

The NeuroVision JJB System (NV JJB) is an electronic device which uses arthroscopic surgical instruments, electrodes, and probes to stimulate nerves with electrical energy, and through the use of electromyography (EMG) electrodes, monitors the sensitivity, and assists in determining the location of nerves during percutaneous surgery of the spine.

The device employs a "Detection" routine which directs brief electrical stimulus pulses through the distal tip of the NuVasive Dilating Cannula as it penetrates tissue to the operative target. Through a series of EMG electrodes placed on the muscle groups associated with the nerves at the operative level of the spine, the NeuroVision JJB System monitors EMG activity in these muscle groups and, when the Cannula tip draws sufficiently near to one such nerve that the electrical energy it emits is strong enough to depolarize the nerve and evoke an EMG response, alerts the surgeon that the Cannula tip is in proximity to that nerve.

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By the same method, a "Direction" routine may be used to sequentially activate four orthogonal stimulation electrodes surrounding the Cannula tip, and thereby determine the direction in which the closest nerve lies. This direction is displayed on a graphical touch screen.

An additional feature of the NeuroVision JJB System is a hand-held electrical probe which is used to ascertain whether a transpedicular screw has violated the pedicle wall. The ball tip of the probe is placed in the screw hole prior to screw insertion or placed on the installed screw head. If the pedicle wall has been breached by the screw or tap, the stimulation current will pass through to the adjacent nerve roots and they will depolarize at a lower stimulation current. The screw test algorithm determines the depolarization (threshold) current for all 8 EMG channels. The surgeon may also set a baseline threshold current by stimulating a nerve root directly with the probe. The surgeon may choose to display the screw test threshold current relative to this baseline.

The NeuroVision JJB System consists of a reusable Patient Module, a Control Unit comprised of an embedded computer with touch screen controls and an interface card, and an assortment of disposable and reusable conductive probe cables, electrodes, and electrode leads.

Intended use:

The NeuroVision JJB System is intended to provide intraoperative electromyographic (EMG) surveillance to assist in the location of nerves during percutaneous surgery of the spine, by administration of brief electrical stimulus pulses to tissues and nerves at the operative site, and EMG monitoring of muscle groups associated with those nerves. The NeuroVision JJB System is designed for use in conjunction with the NuVasive guided spinal arthroscopy system to assist in gaining controlled percutaneous access to the foramina, intervertebral disc, and surrounding tissues of the spine via uniportal or biportal posterior or posterolateral approach, where anatomical restrictions safely permit.

Summary of technological characteristics:

The NeuroVision JJB System has Indications for Use which are identical to the predicate device, is composed of the same or equivalent materials, has equivalant design features, and has functional characteristics which are equivalent. The user interface is via touch screen display replacing the LED display and push button interface of the previous device, and the use of a hard drive allows recording system parameters during use.

Due to the equivalency of indications for use, materials of composition, design features, method of use, and functional characteristics, the device raises no new safety or effectiveness issues.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

OCT 1 6 2001

Mr. Sean Curry
Chief Operating Officer
Certified Software Solutions, Inc.
16787 Bernardo Center Drive
Suite A
San Diego, California 92128

Re: K013215
Trade Name: Neuro Vision JJB System
Regulation Number: 868.2775
Regulation Name: Electrical peripheral nerve stimulator
Regulatory Class: Class II
Product Code: BXM
Dated: September 25, 2001
Received: September 26, 2001

Dear Mr. Curry:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4659. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

Susan Walker MD

Celia M. Witten, Ph.D., MD
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K013215

Device Name: *NuVasive NeuroVision JJB System*

Indications for Use:

The NeuroVision JJB System is intended to provide intraoperative electromyographic (EMG) surveillance to assist in the location of nerves during percutaneous surgery of the spine, by administration of brief electrical stimulus pulses to tissues and nerves at the operative site, and EMG monitoring of muscle groups associated with those nerves. The NeuroVision JJB System is designed for use in conjunction with the NuVasive guided spinal arthroscopy system to assist in gaining controlled percutaneous access to the spinal nerve root, foramina, intervertebral disc, and surrounding tissues of the spine via uniportal or biportal posterior or posterolateral approach, where anatomical restrictions safely permit.

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of General, Restorative
and Neurological Devices

K013215

Prescription Use ✓ OR Over-the-Counter Use
(Per 21 CFR 801.109)

510(k) Number